



JFW
PATENT
Customer No. 22,852
Attorney Docket No. 09138.0045-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Lars WINTHER et al.)	Group Art Unit: 1641
)	
Application No.: 10/563,820)	Examiner: To Be Assigned
)	
Filed: January 6, 2006)	
)	
For: REFERENCE STANDARD FOR)	
DIAGNOSTIC APPLICATIONS)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Office the documents listed on the attached PTO/SB/08 Form. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed non-U.S. patent documents are attached. With respect to the non-English documents listed on the SB/08 Form, Applicants provide the following information:

EP 0622378 A1 is in the same patent family as US 5,990,245, which is also listed on the form.

EP 0630908 A1 is in the same patent family as US 5,453,472, which is also listed on the form.

EP 0628614 A1 and EP0628610 A1 are in the same patent family as US 5,418,304, which is also listed on the form.

EP 0622449 A2 is in the same patent family as US 5,575,946, which is also listed on the form.

EP 0626430 A1 is in the same patent family as US 5,516,546, which is also listed on the form.

EP 0625529 A1 is in the same patent family as CA 2,123,537, which is also listed on the form and provided herewith.

The title and abstract of French document S. Avrameas et al., C.R. Acad. Sci. Paris, Vol. 262 (Serie D): 2543-2545 (1966), are as follows:

Title: Method of labeling antigens and antibodies with enzymes and application in immunodiffusion

Abstract: Antigens and antibodies are coupled with enzymes. The catalytic activity of the associated enzyme allows immunologic complexes to be revealed. In this way, human serum albumin-peroxidase and thymidine-trypsin have allowed the detection, after immuno-electrophoretic analysis, of the anti-albumin and anti-thymidine homologous antibodies. Anti-albumin antibodies were associated with the peroxidase and used, in double diffusion, to detect albumin.

Applicants respectfully request that the Office consider the listed documents and indicate that they were considered by making appropriate notations on the attached PTO/SB/08 Form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed

documents are material or constitute "prior art." If the Office applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

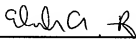
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 6, 2007

By: 
Elizabeth A. Doherty
Reg. No. 50,894

IDS Form PTC/SB/08: Substitute for form 1449A/PTO			Complete if Known Application Number 10/563,820 Filing Date January 6, 2006 First Named Inventor Lars WINTHER Art Unit 1641 Examiner Name To Be Assigned Attorney Docket Number 09138.0045-00	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				
Sheet	1	of	4	



U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		4,376,110	03/08/1983	G. DAVID et al.	
		2,879,178	03/24/1959	P. McWHERTER et al.	
		3,037,006	05/29/1962	E. HANKINS et al.	
		3,502,627	03/24/1970	J. DUPONT et al.	
		3,037,969	06/05/1962	E. HANKINS et al.	
		3,497,485	02/24/1970	W. EMMONS et al.	
		5,990,245	11/23/1999	E. ESSELBORN et al.	
		5,453,472	9/26/1995	A. DECKERS et al.	
		5,418,304	5/23/1995	M. MUELLER et al.	
		5,575,946	11/19/1996	R. BECK et al.	
		5,516,546	5/14/1996	S. HARI et al.	

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		WO 00/62064	10/19/2000	S. BOGEN et al.		
		EP 0623679 A1	11/09/1994	J. HUSTON et al.		
		EP 0368684 A1	05/16/1990	G. WINTER et al.		
		EP 0436597 B1	04/02/1997	R. LADNER et al.		
		EP 0239400 B1	03/08/1994	G. WINTER		
		WO 90/07861	07/26/1990	C. QUEEN et al.		
		EP 0622378 A1	11/02/1994	E. ESSELBORN et al.		NO
		EP 0634428 A2	01/18/1995	P. KIMPTON et al.		
		EP 0623632 A2	11/09/1994	T. AMANO et al.		
		EP 0635522 A1	01/25/1995	J. DA LIO et al.		
		EP 0633273 A1	01/11/1995	T. UEDA et al.		
		EP 0632157 A1	01/04/1995	I. ONO et al.		
		EP 0630908 A2	12/28/1994	A. DECKERS et al.		NO
		EP 0630641 A1	12/28/1994	L. H. TATEOSIAN et al.		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known Application Number 10/563,820 Filing Date January 6, 2006 First Named Inventor Lars WINTHER Art Unit 1641 Examiner Name To Be Assigned Attorney Docket Number 09138.0045-00	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)					
Sheet	2	of	4		

FOREIGN PATENT DOCUMENTS					
	EP 0628614 A1	12/14/1994	M. MUELLER et al.		NO
	EP 0628610 A1	12/14/1994	M. BREHM et al.		NO
	EP 0622449 A2	11/02/1994	R. BECK et al.		NO
	EP 0626430 A1	11/30/1994	S. HARI et al.		NO
	EP 0625529 A1	11/23/1994	D. MARGOTTE et al.		NO
	CA 2,123,537	11/19/1994	D. MARGOTTE et al.		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation	
		S. SOMPURAM et al., "Synthetic Peptides Identified from Phage-displayed Combinatorial Libraries as Immunodiagnostic Assay Surrogate Quality-Control Targets," <i>Clinical Chemistry</i> , Vol. 48 (3): 410-420 (2002).		
		J. VAUGHN et al., "The establishment of two cell lines from the insect <i>Spodoptera frugiperda</i> (Lepidoptera: Noctuidae)," <i>In Vitro</i> , Vol. 13 (4): 213-217 (1977).		
		T. PUCK et al., "Genetics of somatic mammalian cells III. Long-Term Cultivation of Euploid Cells from Human and Animal Subjects," <i>J. Exp. Med.</i> , Vol. 108: 945-956 (1958).		
		M. PEGRAM et al., "Inhibitory effects of combinations of HER-2/neu antibody and chemotherapeutic agents used for treatment of human breast cancers," <i>Oncogene</i> , Vol. 18: 2241-2251 (1999).		
		A. ARGIRIS et al., "Synergistic interactions between Tamoxifen and Herceptin™," <i>Proc. Am. Assoc. Cancer Res.</i> , Vol. 41: 718 (2000) (Abstract).		
		R. PIETRAS et al., "Antibody to HER-2/neu receptor blocks DNA repair after cisplatin in human breast and ovarian cancer cells," <i>Oncogene</i> , Vol. 9: 1829-1838 (1994).		
		J. BASELGA et al., "Recombinant Humanized anti-HER2 Antibody (Herceptin™) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts," <i>Cancer Res.</i> , Vol. 58: 2825-2831 (1998).		
		M. SŁIWKOWSKI et al., "Nonclinical Studies Addressing the Mechanism of Action of Trastuzumab (Herceptin)," <i>Semin. Oncol.</i> , Vol. 26(4) (suppl.12): 60-70 (1999).		
		G. LEWIS et al., "Differential responses of human tumor cell lines to anti-p185 ^{HER2} monoclonal antibodies," <i>Cancer Immunol. Immunother.</i> , Vol. 37: 255-263 (1993).		
		M. PEGRAM et al., "Antibody dependent cell-mediated cytotoxicity in breast cancer patients in Phase III clinical trials of a humanized anti-HER2 antibody," <i>Proc. Am. Assoc. Cancer Res.</i> , Vol. 38: 602 (1997) (Abstract).		
		F. ALTMANN et al., "Insect cells as hosts for the expression of recombinant glycoproteins," <i>Glycoconjugate Journal</i> , Vol. 16: 109-123 (1999).		
		T. KOST et al., "Recombinant baculoviruses as expression vectors for insect and mammalian cells," <i>Curr. Opin. Biotechnol.</i> , Vol. 10: 428-433 (1999).		
		G. KOHLER et al., "Continuous cultures of fused cells secreting antibody of predefined specificity," <i>Nature</i> Vol. 256: 495-497 (1975).		
		L. RIECHMANN et al., "Reshaping human antibodies for therapy," <i>Nature</i> 332: 323-327 (1988).		
		S-R. SHI et al., "Antigen Retrieval Immunocytochemistry: Past, Present and Future," <i>J. Histochem. & Cytochem.</i> , Vol. 45 (3): 327-343 (1997).		
		P. WESTON et al., "Conjugation of Enzymes to Immunoglobulins using Dimaleimides," <i>Biochem. & Biophys. Acta</i> , Vol. 612: 40-49 (1980).		
Examiner Signature		Date Considered		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known

Application Number	10/563,820
Filing Date	January 6, 2006
First Named Inventor	Lars WINTHER
Art Unit	1641
Examiner Name	To Be Assigned
Attorney Docket Number	09138.0045-00

NON PATENT LITERATURE DOCUMENTS

- A. HOWARD et al., "Covalent Labeling of Opioid Receptors with Radiolabeled Human β -Endorphin," *J. Biological Chemistry*, Vol. 260(19): 10833-10839 (1995).
- W. LEE et al., "The murine lymphocyte receptor for IgE III. Use of Chemical Cross-Linking Reagents to Further Characterize the B Lymphocyte Fc Receptor," *J. Immunology*, Vol. 134(1): 518-525 (1985).
- S. D'SOUZA et al., "Chemical Cross-Linking of Arginyl-Glycyl-Aspartic Acid Peptides to an Adhesion Receptor on Platelets," *J. Biological Chemistry*, Vol. 263 (8): 3943-3951 (1988).
- N. GEISLER et al., "Chemical cross-linking indicates a staggered and antiparallel protofilament of desmin intermediate filaments and characterizes one higher-level complex between protofilaments," *Eur. J. Biochem.*, Vol. 206: 841-852 (1992).
- M. MOENNER et al., "Evidence and characterization of the receptor to eye-derived growth factor I, the retinal form of basic fibroblast growth factor, on bovine epithelial lens cells," *Proc. Natl. Acad. Sci. USA*, Vol. 83: 5024-5028 (1986).
- T. YANAGI et al., "Biological activities of semisynthetic analogs of dinophysistoxin-3, the major diarrhetic shellfish toxin," *Agric. Biol. Chem.*, Vol. 53: 525-529 (1989).
- R.J.S. DUNCAN et al., "A New Reagent Which May be Used to Introduce Sulfhydryl Groups into Proteins, and Its Use in the Preparation of Conjugates for Immunoassay," *Analytical Biochemistry*, Vol 132: 68-73 (1983).
- T. KITAGAWA et al., "Enzyme immunoassays of kanamycin group antibiotics with high sensitivities using anti-kanamycin as a common antiserum: reasoning and selection of a heterologous enzyme label," *J. Biochem.*, 94: 1165-1172 (1983).
- K. RUSIN et al., "Immobilization of flavoproteins on silicon: Effect of cross-linker chain length on enzyme activity," *Biosensors & Bioelectronics*, Vol. 7: 367-373 (1992).
- N. GREEN et al., "Immunogenic Structure of the Influenza Virus Hemagglutinin," *Cell*, Vol. 28: 477-487 (1982).
- H.N. AITHAL et al., "An alternate method utilizing small quantities of ligand for affinity purification of monospecific antibodies," *J. Immunol. Methods*, Vol. 112: 63-70 (1988).
- M. ANNUNZIATO et al., "p-Maleimidophenyl Isocyanate: A Novel heterobifunctional Linker for Hydroxyl to Thiol Coupling," *Bioconjugate Chem.*, Vol. 4: 212-218 (1993).
- D. CARUELLE et al., "Development and Testing of Radio and Enzyme Immunoassays for Acidic Fibroblast Growth Factor (aFGF)," *Analytical Biochemistry*, Vol. 173: 328-339 (1988).
- R.B. MERRIFIELD, "Solid Phase Peptide Synthesis. I. The synthesis of a Tetrapeptide," *J. Am. Chem. Soc.*, Vol. 85: 2149-2154 (1963).
- B. MERRIFIELD, "Solid Phase Synthesis," *Science*, Vol. 232: 341-347 (1986).
- G. BARANY et al., "Solid-phase peptide synthesis: A silver anniversary report," *Int. J. Peptide Protein Res.*, Vol. 30: 705-739 (1987).
- G. FIELDS et al., "Solid phase peptide synthesis utilizing 9-fluorenylmethoxycarbonyl amino acids," *Int. J. Peptide Protein Res.*, Vol. 35: 161-214 (1990).
- G. GRETH et al., "Use of the HLB System in Selecting Emulsifiers for Emulsion Polymerization," *J. Applied Polymer Science*, Vol. 5(14): 135-148 (1961).
- A. ALEXANDER, "Some aspects of Emulsion Polymerisation," *J. Oil Colour Chemists' Assoc.*, Vol. 45: 12-15 (1962).
- E. SCHREIBER, "Rapid detection of octamer binding proteins with 'mini-extracts', prepared from a small number of cells," *Nucleic Acids Research*, Vol.17(15): 6419 (1989) (Single page only).
- S. AVRAMEAS, "Enzyme markers: their linkage with proteins and use in immuno-histochemistry," *Histochem. J.*, Vol. 4: 321-330 (1972).
- P.K. NAKANE et al., "Enzyme-labeled antibodies for the light and electron microscopic localization of tissue antigens," *J. Cell Biology*, Vol. 33: 307-318 (1967).
- P.K. NAKANE et al., "Enzyme-labeled antibodies: preparation and application for the localization of antigens," *J. Histochem. Cytochem.*, Vol. 14 (12): 929-931 (1967).
- S. AVRAMEAS et al., "Methode de marquage d'antigenes et d'anticorps avec ces enzymes et son application en immunodiffusion," *C.R. Acad. Sci. Paris*, Vol. 262 (Serie D): 2543-2545 (1966).

NO

 Examiner
Signature

 Date
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.